



# AGENIX LIMITED

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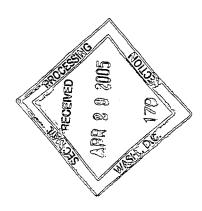
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SUPPL

20 April 2005

US Securities and Exchange Commission Attention: Filing Desk 450 Fifth Street NW **WASHINGTON DC 20549** USA



Dear Sir

# Re: Submission Under Rule 12g3-2(b) - Agenix Limited

We refer to the attached announcement that was made to the Australian Stock Exchange on 20 April 2005.

We are providing a copy of this announcement by virtue of our requirements under Rule 12g3-2(b).

Yours sincerely

DW 5/18

Neil Leggett Company Secretary



# Agenix ThromboView® Update: development remains on schedule

20 April 2005

ThromboView® continues to progress smoothly and rapidly through the development and clinical stages on the road to market. We believe that the performance of the product to date and the progress we have made reinforces the potential that ThromboView® will play a significant role in the diagnosis and management of both DVT and PE patients.

In direct contrast to these and other advancements made by the company, Agenix has been affected in a similar manner to many other stocks in the current biotechnology bear period and our share price has declined to levels last seen over two years ago.

The management and staff of Agenix are committed to continuing to drive our business forward and look forward to your support through this period.

The following update on the status of our ThromboView® program as at the end of March 2005 is intended to assure investors that milestones are being met and to provide guidance on key activities currently underway. As always, key events of a material nature will continue to be communicated as they occur.

For ease of reference, a glossary is included at the end of this update.

In our last update of February 1, 2005 we listed ThromboView<sup>®</sup> developments that we expect to be completed in the next twelve months:

- Injection of first patient in Phase II DVT study in February 2005.
- Release of final report on Phase Ib DVT safety study by March 2005
- Commencement of Phase Ib PE study by May 2005.
- Commencement of Phase II PE study by September 2005
- Negotiation of ThromboView<sup>®</sup> licensing deal with global diagnostic imaging companies.
- Leveraging our clinical and manufacturing capabilities to expand our cardiovascular product pipeline to other cardiovascular conditions (eg stroke) and to other imaging modalities (eg MRI)
- Leveraging our clinical and manufacturing capabilities to expand our product pipeline in other medical areas (eg oncology)

I will take this opportunity to report to you on progress with each of these developments:

## Injection of first patient in Phase II DVT study in February 2005.

The first patient in this study was injected within 72 hours of the site being approved to recruit patients on March 5. Since that time, further sites in the US and Canada have been approved and initiated and additional patients are now enrolled in this study. We will continue to update you when we hit significant milestones throughout the study period.

Clinical trials are a complex and critical component of a drug's passage to market. They must be conceived and undertaken with due concern for the current regulatory environment as regulators will ultimately decide the approvable claims a manufacturer can make about its product. However, a successful clinical program will underpin the realization of both maximum commercial potential and patient benefit. As an example, even though compression ultrasound is the recognized current standard of

patient care for the detection of DVT, the current FDA gold standard for comparison is venography. This procedure is not routinely performed in most hospitals due to the added complexity of the procedure, being invasive and not readily available 24 hours a day. The current DVT trial compares ThromboView® to venography and will provide the basis for our pivotal Phase III trial. Only a positive venogram in the same area as a positive ThromboView® will determine if ThromboView® has the diagnostic accuracy required by FDA to support a claim for diagnosis of DVT.

The D-dimer molecule, which the ThromboView<sup>®</sup> antibody targets, is a measure of clot turnover and thus we believe will provide additional information about the activity state of the clots. We hope to show in this study that ThromboView<sup>®</sup>, will offer doctors a functional imaging test to discern active clot at risk of embolisation from aged clot or clot scar, which is not likely to lead to pulmonary embolism. A venogram of compression ultrasound cannot give doctors information about the functional status of a clot, and research has shown that doctors will value this additional data and allow them to make better diagnostic and treatment decisions for their patients.

## Release of final report on Phase Ib safety study by March 2005

We have produced the final draft of this report and it is currently with the Principal Clinical Investigators of this study for their final review and comments. This report will be filed with the FDA as part of the regular reporting to the open IND and thus forms a very important document in this filing. We will ensure that this document is complete and correct and represents all of the safety data collected in this study prior to submitting to the FDA. The filing of this clinical study report is not on our critical path timeline and the Phase II DVT trial has been initiated with safety data reported from both the Phase Ia study and the interim analysis of the Phase Ib study, filed last year. It will continue irrespective. This trial, as reported previously, has met the primary study endpoints. We will release additional details of the study and the results as soon as the report has finished its review process.

## Commencement of Phase Ib PE study by May 2005

We have filed the study protocol with the FDA as an amendment to the open IND and we are now waiting for any questions or comments the FDA may have. Investigators from all of the trial sites in Australia have attended a Clinical Investigators meeting, convened in mid-March, and the process of preparing the sites, obtaining Ethics approvals and the other necessary items to conduct this trial are well under way and on schedule. We remain confident that we will have the sites actively recruiting patients by May 2005. It is important to note that these trials are voluntary on the patient's part and are also dependant on patients meeting the inclusion criteria set down in the study protocol. These plus other factors will have an impact on the actual recruitment of patients.

# Commencement of Phase II PE study by September 2005

We continue to evaluate the most appropriate clinical trial program to bring ThromboView to market with the correct label claims. We are in discussions with our advisors and clinical investigators to determine the appropriate structure of this trial. When we submit our final trial design to the FDA we will inform you further on this.

# Negotiation of ThromboView® licensing deal with global diagnostic imaging companies.

This process commenced three years ago with meetings and discussions with potential partners. Since that time we have continually achieved our milestones and delivered animal model results, Phase Ia safety study and results, Phase Ib safety study, IND submission and activation and commenced our Phase II DVT trials. This has been on a timeline and to a standard that is similar to any similar biological program at a much larger pharmaceutical company. These discussions will continue and we will share information with these potential partners so that they can evaluate our program and we can evaluate the benefits that we will receive by entering into such arrangements.

Leveraging our clinical and manufacturing capabilities to expand our cardiovascular product pipeline to other cardiovascular conditions (eg stroke) and to other imaging modalities (eg MRI)

It is our intent to critically evaluate the market, potential clinical use, product performance and product specifications for clot-imaging products in the cardiovascular space. This process will take some time but will ensure that any proposed product which is identified in this review process is 'fit for purpose' and meets an unmet medical need.

<u>Leveraging our clinical and manufacturing capabilities to expand our product pipeline in other medical areas (eg oncology)</u>

The team at Agenix has been very active searching, sorting and evaluating potential opportunities in this area. When we find the appropriate potential product we are confident that we will be able to leverage from our past experiences and success to bring this next product to market as quickly as possible.

#### **ENDS**

## For more information contact:

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Agenix Limited [ASX:AGX, NASDAQ OTC: AGXLY] is a global health and biotechnology company based in Brisbane, Australia. The Company runs a suite of highly profitable and established businesses in human and animal health diagnostics, and is focused on growing its world-leading molecular diagnostic imaging R&D program. Agenix's lead candidate is its high-technology ThromboView® blood clot-imaging project, which is currently undergoing human trials. ThromboView® uses radiolabelled antibodies to locate blood clots in the body, and could revolutionise the US \$3 billion global clot diagnostic imaging market. ThromboView® is

being developed with the assistance of the Federal Government through its START scheme. Agenix employs approximately 100 staff and sells its products to more than 50 countries. ThromboView<sup>®</sup> is a registered trademark of AGEN Biomedical.

www.agenix.com

#### Glossary

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DVT Deep vein thrombosis. The formation of blood clots within large veins

(normally in the legs) leading to obstruction of blood flow. DVT can

be painful but not fatal.

FDA Food and Drug Administration. The US government agency

responsible for regulating the food and drug industry. The Australian

equivalent is the Therapeutic Goods Administration (TGA).

IND Investigational New Drug (Application or filing). An IND is reviewed

by the FDA for the suitability and safety of the drug and trial design

for human studies.

Imaging Modalities The method of imaging a disease. X-ray is a common imaging

modality – other modalities include:

- Contrast venography A chemical is injected into the body and imaged with X-ray. The

resulting image can show blockages in those veins. It is a painful and

operator dependant technique.

- CT Computed Tomography. Combines numerous X-ray images into a

single image that is much more precise than conventional X-rays and

provides increased detail.

- MRI Magnetic Resonance Imaging: A large magnet and radio waves use

the electric energy in the body's cells to create an image of structural

defects, especially in soft tissues.

Ultrasound High-frequency sound waves are bounced off soft tissues, and the

echoes are converted into a picture.

PE Pulmonary embolism. The lodgement of clots or other particles in the

blood vessels of the lungs, often as a result of a DVT clot breaking free and traveling through the bloodstream to the lungs. PE can be

fatal.

Phase Ia, Ib, and II New drugs are required to successfully pass three clinical trial phases

before regulators will approve the drug for human use. Very broadly speaking phase I (a and b) determines if the drug is safe, Phase II tests for the appropriate dose, and Phase III provides a final check how well it performs on a larger number of patients before the drug is

commercialised.

Sensitivity and specificity Diagnostic tests need high sensitivity and specificity to give doctors

confidence in the results. Sensitivity is a measure a test's ability to correctly diagnose a patient with a certain disease and specificity is a measure of a test's ability to correctly diagnose a patient who does

not have the disease.